AMJEVITA™ (ADALIMUMAB-ATTO), FIRST BIOSIMILAR TO HUMIRA®, NOW AVAILABLE IN THE UNITED STATES

January 31, 2023

Four Years of Real-World Experience in More Than 300,000 Patients and Over 60 Countries[1]

THOUSAND OAKS, Calif., Jan. 31, 2023 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced AMJEVITA™ (adalimumab-atto), a biosimilar to Humira®* (adalimumab), is now available in the United States. AMJEVITA was the first biosimilar to Humira approved by the U.S. Food and Drug Administration (FDA), in 2016.[2,3]

"With today's announcement, AMJEVITA is the first U.S. biosimilar to Humira®, a medicine used by more than a million patients living with certain serious inflammatory diseases," said Murdo Gordon, executive vice president of Global Commercial Operations at Amgen. "With our track record of developing and manufacturing biologics and decades of experience in inflammation, Amgen is uniquely equipped to supply this biosimilar medicine while reducing costs."

"Biosimilars are extensively studied, FDA-approved treatments that have the potential to reduce costs to the healthcare system," said Steven Taylor, president and chief executive officer at the Arthritis Foundation. "AMJEVITA provides another treatment option for patients and their doctors."

AMJEVITA (40 mg) is available at a list price (Wholesale Acquisition Cost) 55% below the current Humira list price. AMJEVITA is also available at a list price 5% below the current Humira list price. Amgen's goal is to provide broad access for patients by offering two options to health plans and pharmacy benefit managers. More information on Amgen's approach to responsible pricing is on the company's website.

Like Humira's citrate-free formulation that is associated with less pain at the injection site, AMJEVITA is citrate-free.[2,4] AMJEVITA will be available in prefilled syringe and autoinjector presentations to support dosing in each of the approved indications. Amgen offers patient support, such as financial support information and educational resources, through AMJEVITA SupportPlus. To learn more, visit AMJEVITA.com.

Amgen currently has 11 biosimilar medicines in market or under development. Five are FDA-approved in the U.S. and three are approved in the European Union.

About AMJEVITA™ (adalimumab-atto)

AMJEVITA is a biosimilar to Humira®* (adalimumab), an anti-TNF-α monoclonal antibody. The active ingredient of AMJEVITA is an anti-TNF-α monoclonal antibody that has the same amino acid sequence as Humira. AMJEVITA is approved to treat seven inflammatory diseases including moderate-to-severe rheumatoid arthritis in adults, moderate-to-severe polyarticular juvenile idiopathic arthritis in patients 2 years of age and older, psoriatic arthritis in adults, ankylosing spondylitis in adults, moderate-to-severe chronic plaque psoriasis in adults, moderate-to-severe Crohn's disease in adults and pediatric patients 6 years of age and older and moderate-to-severe ulcerative colitis in adults.[2] AMJEVITA outside the U.S. is marketed as AMGEVITA® (adalimumab) and has been prescribed to more than 300,000 patients in over 60 countries.

*Humira® is a registered trademark of AbbVie, Inc.

In the U.S., AMJEVITA is indicated for:

- reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis, alone or in combination with methotrexate or other non-biologic DMARDs.
- reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older, alone or in combination with methotrexate.
- reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis, alone or in combination with non-biologic DMARDs.
- reducing signs and symptoms in adult patients with active ankylosing spondylitis.
- the treatment of moderately to severely active Crohn's disease in adults and pediatric patients 6 years of age and older.
- the treatment of moderately to severely active ulcerative colitis in adult patients. The effectiveness of adalimumab products has not been established in patients who have lost response to or were intolerant to TNF blockers.
- the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate. AMJEVITA should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician.

AMJEVITA ™U.S. Important Safety Information

SERIOUS INFECTIONS

Patients treated with AMJEVITA are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

Discontinue AMJEVITA if a patient develops a serious infection or sepsis.

Reported infections include:

- **Active tuberculosis (TB), including reactivation of latent TB. Patients with TB have frequently presented with disseminated or extrapulmonary disease. Test patients for latent TB before AMJEVITA use and during therapy. Initiate treatment for latent TB prior to AMJEVITA use.**
- **Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Consider empiric anti-fungal therapy in patients at risk for invasive fungal infections who develop severe systemic illness.**
- **Bacterial, viral, and other infections due to opportunistic pathogens, including Legionella and Listeria.**

Carefully consider the risks and benefits of treatment with AMJEVITA prior to initiating therapy in patients: 1. with chronic or recurrent infection, 2. who have been exposed to TB, 3. with a history of opportunistic infection, 4. who resided in or traveled in regions where mycoses are endemic, 5. with underlying conditions that may predispose them to infection. Monitor patients closely for the development of signs and symptoms of infection during and after treatment with AMJEVITA, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

- Do not start AMJEVITA during an active infection, including localized infections.
- Patients older than 65 years, patients with co-morbid conditions, and/or patients taking concomitant immunosuppressants may be at greater risk of infection.
- If an infection develops, monitor carefully and initiate appropriate therapy.
- Drug interactions with biologic products: A higher rate of serious infections has been observed in rheumatoid arthritis (RA) patients treated with rituximab who received subsequent treatment with a TNF blocker. An increased risk of serious infections has been seen with the combination of TNF blockers with anakinra or abatacept, with no demonstrated added benefit in patients with RA. Concomitant administration of AMJEVITA with other biologic DMARDs (e.g., anakinra or abatacept) or other TNF blockers is not recommended based on the possible increased risk for infections and other potential pharmacological interactions.

MALIGNANCY

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers including adalimumab products. Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma, have been reported in patients treated with TNF blockers including adalimumab products. These cases have had a very aggressive disease course and have been fatal. The majority of reported TNF-blocker cases have occurred in patients with Crohn's disease or ulcerative colitis and the majority were in adolescent and young adult males. Almost all of these patients had received treatment with azathioprine or 6-mercaptopurine concomitantly with a TNF blocker at or prior to diagnosis. It is uncertain whether the occurrence of HSTCL is related to use of a TNF blocker or a TNF blocker in combination with these other immunosuppressants.

- Consider the risks and benefits of AMJEVITA prior to initiating or continuing therapy in a patient with known malignancy.
- In clinical trials of some TNF blockers, including adalimumab products, more cases of malignancies were observed among TNF-blocker-treated patients compared to control patients.
- Non-melanoma skin cancer (NMSC) was reported during clinical trials for adalimumab-treated patients. Examine all patients, particularly those with a history of prolonged immunosuppressant or PUVA therapy, for the presence of NMSC prior to and during treatment with AMJEVITA.
- In adalimumab clinical trials, there was an approximate 3-fold higher rate of lymphoma than expected in the general U.S. population. Patients with chronic inflammatory diseases, particularly those with highly active disease and/or chronic exposure to immunosuppressant therapies, may be at higher risk of lymphoma than the general population, even in the absence of TNF blockers.
- Postmarketing cases of acute and chronic leukemia were reported with TNF blocker use. Approximately half of the postmarketing cases of malignancies in children, adolescents, and young adults receiving TNF blockers were lymphomas; other cases included rare malignancies associated with immunosuppression and malignancies not usually observed in children and adolescents.

HYPERSENSITIVITY

Anaphylaxis and angioneurotic edema have been reported following administration of adalimumab products. If a serious allergic reaction occurs, stop AMJEVITA and institute appropriate therapy.

HEPATITIS B VIRUS REACTIVATION

Use of TNF blockers, including AMJEVITA, may increase the risk of reactivation of hepatitis B virus (HBV) in patients who are chronic carriers. Some cases have been fatal. Evaluate patients at risk for HBV infection for prior evidence of HBV infection before initiating TNF blocker therapy. Exercise caution in patients who are carriers of HBV and monitor them during and after AMJEVITA treatment. Discontinue AMJEVITA and begin antiviral therapy in patients who develop HBV reactivation. Exercise caution when resuming AMJEVITA after HBV treatment.

NEUROLOGIC REACTIONS

TNF blockers, including adalimumab products, have been associated with rare cases of new onset or exacerbation of central nervous system and peripheral demyelinating diseases, including multiple sclerosis, optic neuritis, and Guillain-Barré syndrome. Exercise caution when considering AMJEVITA for patients with these disorders; discontinuation of AMJEVITA should be considered if any of these disorders develop.

HEMATOLOGICAL REACTIONS

Rare reports of pancytopenia, including aplastic anemia, have been reported with TNF blockers. Medically significant cytopenia has been infrequently reported with adalimumab products. Consider stopping AMJEVITA if significant hematologic abnormalities occur**.**

CONGESTIVE HEART FAILURE

Worsening or new onset congestive heart failure (CHF) has been reported with TNF blockers. Cases of worsening CHF have been observed with adalimumab products; exercise caution and monitor carefully.

AUTOIMMUNITY

Treatment with adalimumab products may result in the formation of autoantibodies and, rarely, in development of a lupus-like syndrome. Discontinue treatment if symptoms of a lupus-like syndrome develop.

IMMUNIZATIONS

Patients on AMJEVITA should not receive live vaccines. Pediatric patients, if possible, should be brought up to date with all immunizations before initiating AMJEVITA therapy. Adalimumab is actively transferred across the placenta during the third trimester of pregnancy and may affect immune response in the in utero exposed infant. The safety of administering live or live-attenuated vaccines in infants exposed to adalimumab products in utero is unknown. Risks and benefits should be considered prior to vaccinating (live or live-attenuated) exposed infants**.**

ADVERSE REACTIONS

The most common adverse reactions in adalimumab clinical trials (>10%) were: infections (e.g., upper respiratory, sinusitis), injection site reactions, headache, and rash.

Please see the accompanying AMJEVITA full Prescribing Information, including Medication Guide.

About Amgen
Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

Amgen focuses on areas of high unmet medical need and leverages its expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer since 1980, Amgen has grown to be one of the world's leading independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

Amgen is one of the 30 companies that comprise the Dow Jones Industrial Average and is also part of the Nasdaq-100 index. In 2022, Amgen was named one of the "World's Best Employers" by Forbes and one of "America's 100 Most Sustainable Companies" by Barron's.

For more information, visit Amgen.com and follow us on Twitter, LinkedIn, Instagram, TikTok and YouTube.

Amgen Forward-Looking Statements
This news release contains forward-looking statements that are based on the current expectations and beliefs of Amgen. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including any statements on the outcome, benefits and synergies of collaborations, or potential collaborations, with any other company (including BeiGene, Ltd., Kyowa-Kirin Co., Ltd., or any collaboration to manufacture therapeutic antibodies against COVID-19), the performance of Otezla® (apremilast) (including anticipated Otezla sales growth and the timing of non-GAAP EPS accretion), the Five Prime Therapeutics, Inc. acquisition, the Teneobio, Inc. acquisition, the ChemoCentryx, Inc. acquisition, or the proposed acquisition of Horizon Therapeutics plc, as well as estimates of revenues, operating margins, capital expenditures, cash, other financial metrics, expected legal, arbitration, political, regulatory or clinical results or practices, customer and prescriber patterns or practices, reimbursement activities and outcomes, effects of pandemics or other widespread health problems such as the ongoing COVID-19 pandemic on our business, and other such estimates and results. Forward-looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission reports filed by Amgen, including our most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and current reports on Form 8-K. Unless otherwise noted, Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

No forward-looking statement can be guaranteed and actual results may differ materially from those we project. Discovery or identification of new product candidates or development of new indications for existing products cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate or development of a new indication for an existing product will be successful and become a commercial product. Further, preclinical results do not guarantee safe and effective performance of product candidates in humans. The complexity of the human body cannot be perfectly, or sometimes, even adequately modeled by computer or cell culture systems or animal models. The length of time that it takes for us to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and we expect similar variability in the future. Even when clinical trials are successful, regulatory authorities may question the sufficiency for approval of the trial endpoints we have selected. We develop product candidates internally and through licensing collaborations, partnerships and joint ventures. Product candidates that are derived from relationships may be subject to disputes between the parties or may prove to be not as effective or as safe as we may have believed at the time of entering into such relationship. Also, we or others could identify safety, side effects or manufacturing problems with our products, including our devices, after they are on the market.

Our results may be affected by our ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments involving current and future products, sales growth of recently launched products, competition from other products including

biosimilars, difficulties or delays in manufacturing our products and global economic conditions. In addition, sales of our products are affected by pricing pressure, political and public scrutiny and reimbursement policies imposed by third-party payers, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends toward managed care and healthcare cost containment. Furthermore, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. Our business may be impacted by government investigations, litigation and product liability claims. In addition, our business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. If we fail to meet the compliance obligations in the corporate integrity agreement between us and the U.S. government, we could become subject to significant sanctions. Further, while we routinely obtain patents for our products and technology, the protection offered by our patents and patent applications may be challenged, invalidated or circumvented by our competitors, or we may fail to prevail in present and future intellectual property litigation. We perform a substantial amount of our commercial manufacturing activities at a few key facilities, including in Puerto Rico, and also depend on third parties for a portion of our manufacturing activities, and limits on supply may constrain sales of certain of our current products and product candidate development. An outbreak of disease or similar public health threat, such as COVID-19, and the public and governmental effort to mitigate against the spread of such disease, could have a significant adverse effect on the supply of materials for our manufacturing activities, the distribution of our products, the commercialization of our product candidates, and our clinical trial operations, and any such events may have a material adverse effect on our product development, product sales, business and results of operations. We rely on collaborations with third parties for the development of some of our product candidates and for the commercialization and sales of some of our commercial products. In addition, we compete with other companies with respect to many of our marketed products as well as for the discovery and development of new products. Further, some raw materials, medical devices and component parts for our products are supplied by sole third-party suppliers. Certain of our distributors, customers and payers have substantial purchasing leverage in their dealings with us. The discovery of significant problems with a product similar to one of our products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on our business and results of operations. Our efforts to collaborate with or acquire other companies, products or technology, and to integrate the operations of companies or to support the products or technology we have acquired, may not be successful. A breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of our systems and our data. Our stock price is volatile and may be affected by a number of events. Our business and operations may be negatively affected by the failure, or perceived failure, of achieving our environmental, social and governance objectives. The effects of global climate change and related natural disasters could negatively affect our business and operations. Global economic conditions may magnify certain risks that affect our business. Our business performance could affect or limit the ability of our Board of Directors to declare a dividend or our ability to pay a dividend or repurchase our common stock. We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.

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